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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,926	05/09/2006	Koki Endo	OKA-0233	2204
23353 7590 09/20/2007 RADER FISHMAN & GRAUER PLLC LION BUILDING 1233 20TH STREET N.W., SUITE 501 WASHINGTON, DC 20036			EXAMINER DESAI, ANAND U	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 09/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/578,926

**Applicant(s)**

ENDO ET AL.

**Examiner**

Anand U. Desai, Ph.D.

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 15-19, 34-38, 40 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 20-33 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date  
:20060509;20060921;20070629;20060707.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of group I, drawn to a method of synthesizing a protein in a cell-free system using an extract liquid for cell-free protein synthesis in the reply filed on June 29, 2007 is acknowledged. The traversal is on the ground(s) that the search and examination of the entire application could be made without a serious burden. This is not found persuasive because the restriction/election is in accordance with 37 CFR 1.499, Lack of unity of invention during the national stage. The inventions lack the same or corresponding special technical feature, as it does not define a contribution over the prior art. The election of insect cells as the species for prosecution on the merits is acknowledged. Applicants' state that claims 1-14, 20-33, and 39 are readable on the elected subject matter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15-19, 34-38, 40, and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 29, 2007.

3. Claims 1-14, 20-33, and 39 are currently under examination.

### ***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The priority date is November 13, 2003.

***Information Disclosure Statement***

5. The information disclosure statements (IDSs) submitted on May 9, 2006, September 21, 2006, and June 29, 2007 are being considered by the examiner. The IDS submitted on July 7, 2006 is a duplication of the full translation of PCT/JP2004/017219 that was submitted with the IDS submitted September 21, 2006. Therefore, the July 7, 2006 IDS is not being initialed.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1656

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-14, 20-33, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US 2002/0168706) in view of Suzuki et al. (Develop. Growth & Differ. 32(2): 179-187 (1990)), Higashide et al. (U.S. Patent 7,189,528), and Brennan et al. (The Journal of Cell Biology 87: 516-520 (1980)).

Chatterjee et al. disclose compositions, systems and methods for in vitro protein synthesis systems, including coupled translation/transcription systems and uncoupled translation systems. The preferred systems comprise at least a cell extract, at least an energy source and at least one nucleic acid template (see [0037]). Chatterjee et al. further define a preferred system as having enzyme inhibitors, nucleotides, polymerases, cofactors, amino acids, and RNA (see [0042]). Chatterjee et al. disclose that cell extracts are desirable for coupled translation/transcription systems and uncoupled translation systems because the extract is processed to remove cellular debris that could complicate protein purification. The cell extract advantageously contains all of the components needed for protein expression (see [0079]). Chatterjee et al. disclose that the extract can be made from any suitable cells. Suitable cells are those that have components for protein and/or nucleic acid synthesis (see [0100]). The cells are bacterial, animal, fungal or yeast cells. Preferred animal host cells are insect cells such as *Spodoptera frugiperda* cell lines (see [0100]).

Suzuki et al. disclose the transcription of Fibroin and Sericin-1 genes in cell-free extract from various parts of *Bombyx mori*. Extracts were prepared from whole cell and posterior silk

Art Unit: 1656

gland *Bombyx mori*. Covalently joined circular DNAs were used as templates to produce Fibroin and Sericin-1 gene transcripts (see page 182, left column, 1<sup>st</sup> paragraph).

Higashide et al. disclose a cell-free protein synthesis that permits glycosylation after translation into a protein. Higashide et al. disclose a method for cell-free protein synthesis, which comprises subjecting an extract solution, which comprises at least an extract derived from a *Bombyx mori* L. tissue and a reaction mixture comprising at least potassium salt, magnesium salt, dithiothreitol, adenosine triphosphate, guanosine triphosphate, creatine phosphate, creatine kinase, amino acids, Rnase inhibitor, tRNA and a buffer, to conditions suitable for protein synthesis to produce the protein (see claims 1, and 13).

Brennan et al. disclose the processing of vitellogenin polypeptides in cell-free protein expression systems in the presence of arthropod-derived microsomal membranes (see entire document, particularly page 517, Materials and Methods, Preparation of Microsomal Membranes, and page 519, Figure 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize a protein or posttranslationally modify a protein in a cell-free system using an extract from arthropod derived tissue, because Higashide et al. disclose the use of an arthropod derived tissue extract, *Bombyx mori* L. tissue to synthesize glycosylated proteins. It would have been obvious to one of ordinary skill in the art at the time the invention was made to synthesize a protein or posttranslationally modify a protein in a cell-free system using an extract from arthropod derived tissue in the presence of an arthropod-derived microsomal membrane, because Brennan et al. describes the use of microsomal membranes for processing of in vitro

Art Unit: 1656

translated proteins. Additional motivation to use arthropod cell-free systems is provided by the known desire to produce high yields of recombinant proteins in insect cells.

Furthermore in reference to the rejection of claims 2, 3, 21, and 22, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

### ***Conclusion***

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 15, 2007

AD  
/Anand Desai/  
Patent Examiner  
Art Unit 1656